



## **CRS Report for Congress**

# **Extensively Drug-Resistant Tuberculosis (XDR-TB): Quarantine and Isolation**

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### **Summary**

The recent international saga of a traveler with XDR-TB, a drug-resistant form of tuberculosis, has placed a spotlight on existing mechanisms to contain contagious disease threats and raised numerous legal and public-health issues. This report will briefly address the existing law relating to quarantine and isolation, with an emphasis on the interaction of state and federal laws and international agreements. It will not be updated.

### **Background**

On May 12, 2007, a man with tuberculosis flew from Atlanta, Georgia, to Paris, France. After his wedding in Greece, he went to Rome, Italy, where he was contacted by the Centers for Disease Control and Prevention (CDC) and told that he had XDR-TB, a drug-resistant form of tuberculosis with a cure rate of approximately 30%-50%.<sup>1</sup> He was told that he should not get on an airplane and that his passport was the subject of a no-fly order. However, fearing he would not be able to return to the United States for treatment, he flew to Canada and entered the United States by car on May 24. Although CDC had alerted the Atlanta office of Customs and Border Protection in the Homeland Security Department, he was not stopped at the border. CDC contacted him and he voluntarily went to a hospital in New York. He was then flown to an Atlanta hospital. CDC issued a federal order of isolation under the Public Health Service Act, the first since 1963. The patient was flown to the National Jewish Medical and Research Center in Denver for treatment. All tests on the patient have indicated that he posed a low, but possible, risk of transmitting the infection. American citizens who were most at risk in the airplanes the patient traveled on are being contacted.<sup>2</sup>

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<sup>1</sup> For a discussion of XDR-TB see CDC, "Extensively Drug-Resistant Tuberculosis (XDR TB)" [<http://www.cdc.gov/tb/pubs/tbfactsheets/xdrtb.htm>].

<sup>2</sup> CDC, "Questions and Answers: XDR TB in Traveler, from May 30, 2007, CDC Press (continued...)"

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## Federal Quarantine and Isolation Authority

Although the terms are often used interchangeably, quarantine and isolation are two distinct concepts.<sup>3</sup> Quarantine typically refers to the “(s)eparation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection.”<sup>4</sup> Isolation refers to the “(s)eparation of infected individuals from those who are not infected.”<sup>5</sup> Primary quarantine authority typically resides with state health departments and health officials; however, the federal government has jurisdiction over interstate and border quarantine.

Federal quarantine and isolation authority may be found in Section 361 of the Public Health Service Act, 42 U.S.C. § 264, wherein Congress has given the Secretary of Health and Human Services (HHS) the authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”<sup>6</sup> Executive Order 13295 lists the communicable diseases for which this quarantine authority may be exercised and specifically includes infectious tuberculosis.<sup>7</sup> In 2000, the Secretary of HHS transferred certain authorities, including interstate quarantine authority, to the Director of the CDC.<sup>8</sup> Both interstate and foreign quarantine measures are now carried out by CDC’s Division of Global Migration and Quarantine.<sup>9</sup> However, it should be noted that while the federal government has the authority to authorize quarantine and isolation under certain circumstances, the primary authority for quarantine and isolation exists at the state level as an exercise of the state’s police power. CDC acknowledges this deference to state authority as follows:

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<sup>2</sup> (...continued)

Conference,” [http://www.cdc.gov/tb/xdr/tb/travellerfactsheet.htm]; Lawrence K. Altman, “Agent at Border, Awar, Let in Man with TB,” *The New York Times*, June 1, 2007, [http://www.nytimes.com/2007/06/01/health/01tb.html?\_r=1&ref=health&oref=slogin]; Lawrence K. Altman and John Schwartz, “Near Misses Allowed Man with Tuberculosis to Fly,” *The New York Times*, May 31, 2007, [http://www.nytimes.com/2007/05/31/us/31tb.html?pagewanted=print]. It should be noted that there is some disagreement concerning certain facts, such as whether the traveler was told he should not travel prior to boarding the flight to Paris.

<sup>3</sup> For a detailed discussion of quarantine and isolation, see CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by Kathleen S. Swendiman and Jennifer K. Elsea.

<sup>4</sup> Homeland Security Council, National Strategy for Pandemic Influenza: Implementation Plan 209 (GPO May 2006).

<sup>5</sup> *Id.* at n. 207.

<sup>6</sup> 42 U.S.C. § 264(b).

<sup>7</sup> See [http://www.fas.org/irp/offdocs/eo/eo-13295.htm] and [http://www.whitehouse.gov/news/releases/2005/04/20050401-6.html]

<sup>8</sup> 42 C.F.R. Part 70. Regulations regarding quarantine upon entry into the United States from foreign countries are also administered by the CDC, see 42 C.F.R. Part 71.

<sup>9</sup> See CDC Division of Global Migration and Quarantine home page at [http://www.cdc.gov/ncidod/dq/index.htm].

In general, CDC defers to the state and local health authorities in their primary use of their own separate quarantine powers. Based upon long experience and collaborative working relationships with our state and local partners, CDC continues to anticipate the need to use this federal authority to quarantine an exposed person only in rare situations, such as events at ports of entry or in similar time-sensitive settings.<sup>10</sup>

The CDC on November 22, 2005, announced proposed changes to its quarantine regulations.<sup>11</sup> If adopted, these changes would constitute the first significant revision of the regulations in Parts 70 and 71 in 25 years. The proposed changes are an outgrowth of the CDC's experience during the spread of SARS in 2003, when the agency experienced difficulties locating and contacting airline passengers who might have been exposed to the SARS virus during their travels. In announcing the proposed regulations, CDC Director Julie Gerberding said, "[t]hese updated regulations are necessary to expedite and improve CDC operations by facilitating contact tracing and prompting immediate medical follow up of potentially infected passengers and their contacts."<sup>12</sup> The proposed regulations would expand reporting requirements for ill passengers<sup>13</sup> onboard flights and ships arriving from foreign countries. They would also require airlines and ocean liners to maintain passenger and crew lists with detailed contact information and to submit these lists electronically to CDC upon request.<sup>14</sup> The lists would be used to notify passengers of their suspected exposure if a sick person were not identified until after the travelers had dispersed from an arriving carrier. The proposed regulations address the due process rights of passengers who might be subjected to quarantine after suspected exposure to disease; the regulations also provide for an appeal process.

## International Health Regulations

In May 2005 the World Health Assembly adopted a revision of its 1969 International Health Regulations (IHR), giving a new mandate to the World Health Organization (WHO) and member states to increase their respective roles and responsibilities for the

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<sup>10</sup> Q&A on Executive Order 13295, available at [[http://www.cdc.gov/ncidod/dq/qa\\_influenza\\_amendment\\_to\\_eo\\_13295.htm](http://www.cdc.gov/ncidod/dq/qa_influenza_amendment_to_eo_13295.htm)].

<sup>11</sup> See 70 Fed. Reg. 71892 (November 30, 2005), [<http://www.cdc.gov/ncidod/dq/nprm/>]. These proposed regulations were available for a 60-day comment period, and later extended for an additional 30 days, closing on March 1, 2006. See 71 Fed. Reg. 4544 (January 27, 2006). Proposed section 70.20 and 71.23 of 42 C.F.R.

<sup>12</sup> CDC Proposes Modernizing Control of Communicable Disease Regulation, USA, Medical News Today, November 23, 2005, at [<http://www.medicalnewstoday.com/medicalnews.php?newsid=34042>]. Since the SARS outbreak, the CDC has increased its quarantine stations nationwide from 8 to 18.

<sup>13</sup> The definition of ill person would be expanded to include anyone who has a fever of at least 100.4 degrees plus one of the following: severe bleeding; jaundice; or severe, persistent cough accompanied by bloody sputum, or respiratory distress. (Section 70.1 of proposed regulations.) It should be noted that the traveler with XDR-TB apparently did not have any symptoms.

<sup>14</sup> *Id.* The lists, in electronic format, would have to be kept for 60 days after arrival, and be able to be submitted within 12 hours of a CDC request. The lists would include names, contact information, and seat assignments.

protection of international public health.<sup>15</sup> The IHR(1969) focused on just three diseases (cholera, plague, and yellow fever). In addition, compliance of State Parties<sup>16</sup> with the IHR(1969) was uneven, a result of, among other things, resource limitations in poorer countries, and political factors, such as the reluctance to announce the presence of a contagious disease within one's borders and face economic and other consequences.<sup>17</sup>

The IHR(2005) broaden the scope of the 1969 regulations by addressing existing, new, and re-emergent diseases, as well as emergencies caused by non-infectious disease agents. The IHR(2005) require State Parties to notify WHO of all events that may constitute a "public health emergency of international concern," and to provide information regarding such events.<sup>18</sup> The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and State Parties to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.

The IHR were agreed upon by a consensus process among the member states, and represent a balance between sovereign rights and a commitment to work together to prevent the international spread of disease. The IHR(2005) enter into force and become binding on all WHO member states on June 15, 2007, except for those that have rejected the regulations or submitted reservations.<sup>19</sup> The United States has officially accepted the IHR(2005).<sup>20</sup> Following its entry into force, States Parties have a two-year period to assess the ability of existing national structures and resources for meeting the core surveillance and response capacities requirements set out in the regulations and to develop plans of action to ensure that these capacities are in place. Within five years of the entry into force date, State Parties must complete development of public health infrastructure that ensures full compliance with the regulations.

According to the revised (2005) International Health Regulations, State Parties are not to bar the entry of a conveyance for public health reasons, but are rather to manage the public health threat through isolation, quarantine, disinfection, or other such applicable

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<sup>15</sup> Fifty-eighth World Health Assembly, agenda item 13.1, Revision of the International Health Regulations, May 23, 2005, at [<http://www.who.int/csr/ihr/en/>].

<sup>16</sup> "State Party" is the name for WHO member states that have agreed to be bound by the IHR.

<sup>17</sup> Baker, M.G., Fidler, D.P., "Global Public Health Surveillance under New International Health Regulations," *Emerging Infectious Diseases*, vol. 12, no. 7, July 2006, at [<http://www.cdc.gov/ncidod/EID/bol12no07/05-1497.htm>].

<sup>18</sup> A "public health emergency of international concern" is defined as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response." IHR (2005), Article 1.

<sup>19</sup> IHR(2005), Article 59.2.

<sup>20</sup> HHS Secretary Michael Leavitt announced the acceptance of the IHR(2005) by the United States on December 13, 2006. The United States accepted the regulations with three reservations, including the reservation that it will implement them in line with U.S. principles of federalism. See News Release at [<http://www.pandemicflu.gov/plan/federal/index.html>].

methods.<sup>21</sup> Article 43 of the IHR allows nations to implement additional health measures in accordance with their relevant national law and obligations under international law in response to specific health concerns. If a State Party implements additional health measures significantly interfering with international traffic, the public health rationale and relevant scientific information for the measures must be provided to WHO. The WHO shall share the information with State Parties and institute procedures to find a mutually acceptable solution.<sup>22</sup>

In May 2006, the World Health Assembly, concerned about the potential for an influenza pandemic, called upon State Parties to voluntarily comply, one year early, with those provisions of the IHR(2005) considered relevant for the control of avian and pandemic flu, regarding reporting, information sharing, and other matters.<sup>23</sup> While the IHR(2005) do not include an enforcement mechanism for States Parties that fail to comply with their provisions, the WHO considers the potential consequences of non-compliance within the global community, especially in economic terms, to be a powerful compliance tool.<sup>24</sup> The IHR(2005) (Article 56) contain a dispute settlement mechanism to resolve conflicts which may arise among State Parties when applying or interpreting the regulations, including options such as negotiation, mediation, conciliation, or arbitration, or referral to the Director-General of WHO, if agreed to by all the parties to the dispute.

The World Health Organization (WHO) has issued a document containing guidelines regarding tuberculosis and air travel, which includes a discussion of legal and regulatory issues and notes that airline companies are expected to comply with the IHR and the laws of the countries in which they operate.<sup>25</sup> WHO notes the confidentiality concerns as well as the potential for discrimination charges. Although the IHR(2005) are not yet in force, WHO has indicated that the CDC is carrying out investigations about the traveler with XDR-TB in line with those recommended by these guidelines, and CDC notes that the response to the XDR-TB incident has been consistent with the revised regulations.

One of the difficulties raised by the traveler with XDR-TB was the interaction of the varying state, federal, and international laws, regulations, and authorities. The Director of CDC, Dr. Julie Gerberding, observed that there were difficulties determining how CDC was to use its assets and how the statements of principle in the international health regulations were to be applied in a specific situation to determine, for example, who should pay to move a patient, and who should care for a patient in isolation or quarantine.<sup>26</sup>

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<sup>21</sup> IHR, Article 28.1, “Ships and aircraft at points of entry.”

<sup>22</sup> IHR, Article 43, “Additional Health Measures.”

<sup>23</sup> Fifty-ninth World Health Assembly, agenda item 11.1, Application of the International Health Regulations (2005), May 26, 2006, at [<http://www.who.int/csr/ihr/en/>].

<sup>24</sup> See WHO “Frequently Asked Questions About the International Health Regulations,” at [<http://www.who.int/csr/ihr/howtheywork/faq/en/print/html>].

<sup>25</sup> World Health Organization, “Tuberculosis and Air Travel: Guidelines for Prevention and Control” (2d ed. 2006), [<http://www.who.int/tb/en/>].

<sup>26</sup> CDC “Update on CDC Investigation into People Potentially Exposed to Patient With Extensively Drug Resistant TB,” (June 1, 2007)  
(continued...)

## Civil Rights

The situation presented by the traveler with XDR-TB raises a classic civil rights issue: to what extent can an individual's liberty be curtailed to advance the common good? The Constitution and federal civil rights laws provide for individual due process and equal protection rights as well as a right to privacy, but these rights are balanced against the needs of the community. With the advance of medical treatments in recent years, especially the use of antibiotics, the civil rights of the individual with a contagious disease have been emphasized. However, classic public health measures such as quarantine, isolation, and contact tracing are, nevertheless, available in appropriate situations. The issue is how to balance the various interests.

Under U.S. law, an individual with an infectious disease may be covered by nondiscrimination laws, notably the Americans with Disabilities Act (ADA),<sup>27</sup> Section 504 of the Rehabilitation Act,<sup>28</sup> and the Air Carriers Access Act.<sup>29</sup> However, an individual with a contagious disease does not have to be given access to a place of public accommodation if such access would place other individuals at a significant risk.<sup>30</sup> The Supreme Court dealt with these issues in the context of tuberculosis and Section 504 in *School Board of Nassau County v. Arline*<sup>31</sup> and found that in most cases an individualized inquiry is necessary in order to protect individuals with disabilities from “deprivation based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to such legitimate concerns of grantees as avoiding exposing others to significant health and safety risks.”<sup>32</sup> The Court adopted the test enunciated by the American Medical Association (AMA) amicus brief and held that the factors which must be considered include “findings of facts, based on reasonable medical judgments given the state of medical knowledge, about (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm.” The Court also emphasized that courts “normally should defer to the reasonable medical judgments of public health officials.”<sup>33</sup>

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<sup>26</sup> (...continued)

[<http://www.cdc.gov/od/oc/media/transcripts/2007/t070601.htm>].

<sup>27</sup> 42 U.S.C. §§12101 *et seq.*

<sup>28</sup> 29 U.S.C. §794.

<sup>29</sup> 42 U.S.C. §1374(c).

<sup>30</sup> For a more detailed discussion of this issue see CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by Nancy Lee Jones.

<sup>31</sup> 480 U.S. 273 (1987).

<sup>32</sup> *Id.* at 287.

<sup>33</sup> *Id.* at 288. These standards are incorporated into the regulations for the Air Carriers Access Act at 14 C.F.R. §382.51.